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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/577,607

04/27/2006

W. Charles O'Neill

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EXAMINER

KASSA, TIGABU

ART UNIT

PAPER NUMBER

1619

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/577,607	<b>Applicant(s)</b> O'NEILL ET AL.	
	<b>Examiner</b> TIGABU KASSA	<b>Art Unit</b> 1619	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 August 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 17-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/29/07</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claim 1-34 are pending. Claims 1-16 are under consideration in the instant office action. Claims 17-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claims.

### ***Election/Restrictions***

Applicant's election without traverse of Group I (claims 1-16) in the reply filed on 08/07/09 is acknowledged.

### ***Priority***

The effective filing date of this application has determined to be 10/28/03, the filing date of the provisional application 60/515,174.

### ***Information Disclosure Statement***

The information disclosure statement (IDSs) submitted on 05/29/07 is noted and the submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the references.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-4 and 6-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Feagin et al. (Calc. Tiss. Res. 1969, 4, 231-244).**

Instant claim 1 recites a method of providing vascular calcification therapy to an individual in need of treatment comprising the step of administering to the individual an effective amount of a pyrophosphate-type compound. Instant claim 2 recites the method of claim 1, wherein the pyrophosphate-type compound is an alkali metal pyrophosphate. Instant claim 3-4 recite the method of claim 1, wherein the pyrophosphate-type compound is chosen from the lists recited in the claims. Instant claim 6 recites the method of claim 1, further comprising treating the individual with dialysate. Instant claim 7 recites the method of claim 1, wherein the pyrophosphate-type compound is administered to the individual in a dialysate fluid. Instant claim 8 recites the method of claim 1 wherein the pyrophosphate type compound is administered during dialysis. Instant claims 9-10 recite the method of claim 1, wherein the pyrophosphate-type compound has a structure as recited in the claim. Instant claims 11-13 recite the concentrations of the pyrophosphate compound. Instant claim 14 recites a method of prophylactically treating vascular calcification comprising administering to an individual in need of treatment an effective amount of at least one pyrophosphate-type compound. Instant claim 15 recites the method of claim 14, wherein the pyrophosphate-type compound is an alkali metal pyrophosphate. Instant claim 16 recites the method of claim 14, wherein pyrophosphate-type compound is administered to the individual in a dialysate.

Feagin et al. disclose the use of pyrophosphate as an inhibitor of calcification (abstract; page 234, Evaluation of Relations of Pyrophosphate Ions and Calcification). Tetrasodium pyrophosphate was injected intraperitoneally in rats (page 234, Evaluation of Relations of

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Pyrophosphate Ions and Calcification). Pyrophosphate significantly reduced rehardening of enamel slabs in young animals (page 234, Evaluation of Relations of Pyrophosphate Ions and Calcification). Pyrophosphate concentrations up to 10  $\mu$ M were added to standard calcifying solutions (page 234, Evaluation of Relations of Pyrophosphate Ions and Calcification). The calcifying solution is added to the plasma dialysate (page 236, Fig. 3 legend). The examiner notes that dialysate is used for dialysis, therefore, the pyrophosphate must be administered during dialysis. The effect of pyrophosphate added to calcifying solutions as a concentration of 3.0  $\mu$ M was tested (page 235, figure 2).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Feagin et al. (Calc. Tiss. Res. 1969, 4, 231-244) as applied to claims 1-4 and 6-16 above, and further in view of Qunibi et al. (Kidney International 2002, 62, S73-S80).**

*Applicant Claims*

Instant claim 5 recites the method of claim 1 wherein the vascular calcification is caused by renal disease or failure.

***Determination of the Scope and Content of the Prior Art (MPEP §2141.01)***

The teachings of Feagin et al. are disclosed above.

***Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)***

Although Feagin et al. teach the use of pyrophosphate in dialysate solutions, enamel surfaces were artificially implanted in the rats.

However, Qunibi et al. teach that calcification is known to occur in advanced renal failure (abstract). Pyrophosphate is known to inhibit calcium phosphate precipitation (i.e. calcification, page s74).

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***Finding of Prima Facie Obviousness Rationale and Motivation  
(MPEP §2142-2143)***

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the pyrophosphate to inhibit calcification caused by renal failure since dialysis is used to treat renal failure and Feagin et al. teach the incorporation of pyrophosphate in dialysate. Moreover, Qunibi et al. teach that calcification is known to occur in advanced renal failure (abstract). An ordinary skilled artisan would have been motivated to use pyrophosphate to treat calcification caused by renal failure because both Feagin et al. and Qunibi et al. teach that pyrophosphate is effective for inhibiting calcification. One of ordinary skill in the art at the time of the instant application was filed would have had a reasonable expectation of success in treating calcification caused by renal failure since dialysis is a known treatment for renal failure and Feagin et al. incorporated pyrophosphate in dialysate.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Therefore, the invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

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**Conclusion**

Claim 1-16 are rejected. Claims 17-34 are withdrawn. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa

8/15/09

*/Mina Haghighatian/*

Primary Examiner, Art Unit 1616